

“Business Practice Guidelines” to Advance Translational Research Activities Involving Multiple Institutions

CREDENTIALING

Overview

The reason why credentialing is a matter of concern for multi-institutional collaborations is the need to ensure that researchers can have access to the broad array of resources, such as labs and patients, found across biomedical research institutions in Arizona.

A number of different situations requiring credentials can be expected:

- Credentials for a researcher who is already affiliated with a university or academic health center
- Credentials for an unaffiliated basic researcher
- Credentials for private practice physician to conduct clinical research

Discussion

Credentials for a researcher who is already affiliated with a university or academic health center

This would seem to be more of an issue of the relationship between two institutions and under what circumstances they permit adjunct status or more shared status. For instance, in the case of TGEN and the public research universities in Arizona they decided to designate who is the lead employer for a researcher so that issues of IP, indemnification and insurance could be clearly delineated. In the case of Sun Health Research Institute and ASU, this is more of a traditional arm's length adjunct relationship. VA also seems to create these relationships between specific VA hospitals and local universities.

Credentials for unaffiliated researchers (including non-practicing physicians) with university and academic health center.

If the researcher is unaffiliated with any organization, then the question becomes how does that researcher easily collaborate with a particular organization ... but this in turn seems more of an institution by institution issue related to how it grants adjunct status, and not one of inter-institutional collaboration.

Credentials for private practice physician to conduct clinical research..

In the case of hospitals granting a credential to do clinical research, this seems to be more of an institution-by-institution issue. Most hospitals in Arizona are open credential, so they can easily credential most of those in a private practice. However, for those hospitals and medical centers with a closed private practice group, the opportunity for outside physicians to conduct clinical research is more limited and typically needs to go through review processes to determine if it is in the best interest of the institution.

Guiding Principles and Recommendations:

Credentialing is primarily a matter of how well institutions can reach affiliation agreements, and so is more derivative of the broader business practice issues affecting the ability of institutions to collaborate. The ability of researchers associated with a particular institution to collaborate on-site with researchers of another institution or to access to another institution's key facilities is primarily a matter of the extent and ease in which the two institutions can put in place affiliation agreements. These affiliation agreements must address the key business practice issues of indemnification, IP, overhead rates and insurance coverage.

It would be helpful to establish a broad practice in which those institutions with closed clinical physician practices would allow credentialing for outside partners involved in clinical research. As Arizona seeks to raise the level of clinical research, particularly engaging private practice physicians, then it seems to be critical to set policies in which these private practice physicians can have credentials to conduct clinical research on-site at different institutions with closed physician practices. If this were to happen, then issues of how to address insurance and indemnification coverage would need to be carefully examined to determine if there might be real problems raised in terms of liability and how best to address.